REMARKS OF THE HONORABLE HENRY A. WAXMAN

CHAIRMAN

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT BEFORE THE

TWENTY-FIRST ANNUAL CONSUMER ASSEMBLY
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GOOD AFTERNOON. I AM VERY PLEASED TO BE WITH YOU TODAY.

IT IS ALWAYS REFRESHING TO BE AROUND A LARGE GATHERING OF PEOPLE WHO SHARE SO MANY OF MY CONCERNS ABOUT PEOPLE'S HEALTH AND SAFETY, AND ABOUT WHAT IS AND IS NOT FAIR TO THE CITIZENS OF THIS COUNTRY. WE HAVE WORKED CLOSELY WITH MANY OF YOU AND WITH YOUR WASHINGTON REPRESENTATIVES OVER THE YEARS, AND WE PLACE A HIGH VALUE ON YOUR IDEAS AND YOUR SUPPORT.

TODAY I WILL DISCUSS SEVERAL OF THE AREAS THAT WE ARE CURRENTLY WORKING ON THAT ARE OF SUBSTANTIAL IMPORTANCE TO CONSUMERS.

PRODUCT LIABILITY

FIRST, AN AREA THAT QUITE FRANKLY HAS BEEN BOTH DIFFICULT AND SOMEWHAT DISCOURAGING -- ATTEMPTS TO DRAFT A FEDERAL LAW GOVERNING PRODUCT LIABILITY.

IN RECENT YEARS, THERE WERE A NUMBER OF BILLS THAT WERE INTRODUCED AND DEBATED, LARGELY IN THE SENATE. ALTHOUGH PORTRAYED AS ATTEMPTING TO INTRODUCE NATIONAL UNIFORMITY AND FAIRNESS INTO THE LAW OF PRODUCT LIABILITY, MOST OF THOSE BILLS WERE SIMPLY DESIGNED TO TAKE AWAY FROM INJURED CONSUMERS MANY OF THEIR RIGHTS TO RECOVERY. WE WATCHED THOSE BILLS CAREFULLY, BUT WERE NEVER FACED WITH SERIOUS ACTION IN THE HOUSE.

In this Congress, things have been quite different. The Subcommittee with Jurisdiction over this issue has now reported out a bill that soon will come before the full Committee on Energy and Commerce.

I MUST STATE THAT I AM EXTREMELY DISAPPOINTED THAT THE COMMITTEE IS MOVING TO MARKUP THIS LEGISLATION SO QUICKLY.

The version of the legislation before the Committee was developed behind closed doors and moved through the Subcommittee as a package deal between a handful of Members and Certain representatives of the business community.

IT WAS DEVELOPED WITHOUT SIGNIFICANT INPUT FROM CONSUMER GROUPS, LABOR, OR OTHER INTERESTED PARTIES.

AT THE MARKUP OF THIS BILL BEFORE THE SUBCOMMITTEE, I OFFERED A NUMBER OF AMENDMENTS. I BELIEVE THOSE AMENDMENTS ARE CRITICAL IF THIS DRAFT IS TO BE TRANSFORMED INTO A RESPONSIBLE BALANCE

BETWEEN THE INTERESTS OF MANUFACTURERS AND THOSE OF CONSUMERS WHO ARE INJURED BY DEFECTIVE PRODUCTS.

BUT ALL OF THOSE AMENDMENTS WERE DEFEATED.

WERE THEY DEFEATED ON THEIR MERITS? THAT IS HARD TO ACCEPT, SINCE SEVERAL OF MY AMENDMENTS DID NO MORE THAN PUT INTO STATUTORY LANGUAGE PRECISELY WHAT THE SPONSORS ASSERTED WAS THE PURPOSE OF THIS LEGISLATION -- ENACTING A UNIFORM STANDARD OF STRICT LIABILITY FOR INJURIES CAUSED BY UNREASONABLY DANGEROUS DEFECTIVE PRODUCTS.

This is a complicated bill, on a complex subject. It proposes to assert federal jurisdiction over the law of product liability, an area that traditionally has been under State jurisdiction. It contains many legal terms that will be subject to interpretation in thousands of lawsuits all over the country.

Many of those legal terms differ from closely related terms in State statutes and court cases. But the bill provides no clear statutory guidance as to how those provisions should be interpreted. This can only result in substantial confusion. Will prior State interpretations be sustained or preempted by this statute? No one can say with any clarity.

I BELIEVE THAT SUCH HASTE IN THIS IMPORTANT AREA IS MOST UNFORTUNATE.

AMONG THE PROVISIONS OF PARTICULAR CONCERN TO ME ARE THE FOLLOWING:

- -- CONSUMER RIGHTS ARE SUBSTANTIALLY NARROWED. THOSE THAT

 REMAIN ARE EXCLUSIVELY LIMITED TO THE FEW SET FORTH IN THIS

 BILL. IN SHARP CONTRAST, MANUFACTURERS OF DEFECTIVE PRODUCTS

 ARE GIVEN EXPANDED DEFENSES, LEFT FREE TO INVOKE THOSE

 CURRENTLY AVAILABLE UNDER STATE LAWS AND PERMITTED TO PURSUE

 ADDITIONAL DEFENSES IN STATE COURTS AND LEGISLATURES.
- -- THE LEGAL STANDARD ESTABLISHED IS DESCRIBED AS STRICT
 LIABILITY AS DEFINED IN THE RESTATEMENT (SECOND) OF TORTS,
 BUT THE WORDS DIFFER FROM THOSE IN THE RESTATEMENT AND LEGAL
 SCHOLARS TELL US THAT THE BILL WITH ALL OF ITS DEFENSES
 ESTABLISHES A DIFFERENT STANDARD THAT IS NOT STRICT
 LIABILITY.
- -- STATE CAPS ON DAMAGES AND BARRIERS TO PUNITIVE DAMAGES ARE LEFT IN PLACE, AND MANUFACTURERS ARE FREE TO PURSUE ADDITIONAL ONES AT THE STATE LEVEL.
- -- IN THE DRUG AND MEDICAL DEVICE AREA, THE COMBINATION OF

 DEFENSES AVAILABLE TO BOTH COMPENSATORY AND PUNITIVE DAMAGES

 COULD BE CONSTRUED TO MAKE ANY RECOVERY BY INJURED CONSUMERS

 EXTREMELY UNLIKELY.

- -- THE "STATE-OF-THE-ART" LANGUAGE WITH RESPECT TO A

 MANUFACTURER'S LIABILITY IN DESIGN AND WARNING CASES IS

 AMBIGUOUS IN ITS TERMS AND WOULD IMMUNIZE THE SALE OF MANY
 PRODUCTS EVEN WHERE THE RISKS OUTWEIGH THE BENEFITS.
- -- Unlike other previous bills, the exceptions to manufacturer liability (such as state-of-the-art) are not clearly identified as being defenses where the burden of proof Lies with the defendant manufacturer.
- -- THERE ARE NO PROVISIONS DEALING WITH MANY ISSUES WHERE

 CONSUMERS COULD BENEFIT, SUCH AS MANDATORY RECORDKEEPING,

 COMPARATIVE FAULT, AND SMALL PRODUCT LIABILITY CLAIMS.

IN ADDITION TO ALL THE PROBLEMS RAISED FOR INJURED CONSUMERS,
THIS BILL ALSO FAILS TO ACCOMPLISH THE TWO MOST IMPORTANT
THINGS THAT EVEN THE BUSINESS COMMUNITY HAS ALWAYS LOOKED TO
FEDERAL PRODUCT LIABILITY LEGISLATION FOR -- A UNIFORM
SYSTEM, AND REASONABLE INSURANCE RATES.

- -- THE GOAL OF UNIFORMITY HAS BEEN LEFT ASIDE, EXCEPT THAT

 CONSUMER RIGHTS ARE UNIFORMLY LIMITED TO THE TERMS OF THIS

 LEGISLATION.
- -- THERE IS NO PROVISION WHATSOEVER TO ASSURE THAT THESE DRASTIC MODIFICATIONS OF TORT LAW WILL RESULT IN IMPROVED AVAILABILITY AND LOWER PRICES FOR LIABILITY INSURANCE.

AS CONSUMER ADVOCATES, YOU WILL APPRECIATE THE IRONY IN WHAT WE ARE BEING ASKED TO DO.

WE HAVE MANY TIMES EXPRESSED OUR DISMAY OVER THE WAY THE CONSUMER PRODUCT SAFETY COMMISSION HAS BEEN TURNED INTO AN INEFFECTUAL SHAMBLES AS A RESULT OF YEARS OF RELENTLESS ATTACKS BY THE REAGAN ADMINISTRATION. AND WHAT HAS THEIR RATIONALE BEEN —— "LET THE PRODUCT LIABILITY SYSTEM DEAL WITH PRODUCT SAFETY!"

NOW, IN A BILL DRAFTED AS AN AMENDMENT TO THE CONSUMER PRODUCT SAFETY COMMISSION ACT, WE ARE ABOUT TO EMASCULATE THE PRODUCT LIABILITY SYSTEM AS WELL.

I HAVE BEEN SUPPORTIVE OF EFFORTS TO PROVIDE THIS COMPLEX
AREA WITH THE CAREFUL SCRUTINY AND THOROUGH CONSIDERATION IT
DESERVES. I AM WORKING CLOSELY WITH SEVERAL OF YOUR GROUPS AND
WITH OTHER MEMBERS TO ATTEMPT TO IMPROVE THIS BILL AND OFFER
CONSUMERS WHO ARE KILLED AND INJURED BY DEFECTIVE PRODUCTS A FAIR
CHANCE TO BE COMPENSATED FOR THEIR INJURIES.

THIS HAS NOT BEEN AN EASY FIGHT, BUT WE WILL STAY IN IT NO MATTER WHAT IT TAKES. THE STAKES FOR CONSUMERS ARE TOO GREAT.

MEDICAL DEVICES

ONE OF THE BASIC FUNCTIONS THAT CONSUMERS LOOK TO THE FEDERAL GOVERNMENT FOR IS ASSURING THE SAFETY AND EFFECTIVENESS OF DRUGS AND MEDICAL DEVICES. UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC

ACT, THIS IS THE RESPONSIBILITY OF THE FOOD AND DRUG ADMINISTRATION (FDA).

WHILE PROBLEMS ARISE FROM TIME TO TIME EVEN WITH THE DRUG APPROVAL PROCESS, BY AND LARGE THE FDA DESERVES CREDIT FOR EXTRAORDINARY SUCCESS IN ASSURING THAT OUR MEDICATIONS ARE SAFE AND EFFECTIVE.

I WISH WE COULD SAY THE SAME WITH REGARD TO MEDICAL DEVICES, BUT, UNFORTUNATELY, WE CANNOT.

BEFORE 1976, THE FDA'S AUTHORITY OVER MEDICAL DEVICES WAS LIMITED. IN THAT YEAR, CONGRESS AMENDED THE LAW TO EXPAND FDA'S POWERS DRAMATICALLY. NO DEVICES WERE TRULY "GRANDFATHERED" -- FDA IS REQUIRED TO REGULATE BOTH OLD AND NEW DEVICES.

This new authority placed a great demand on FDA, and I believe they have tried hard to meet their responsibilities. But the combination of a complex and exacting statute and eight years of an Administration that has slashed the resources of regulatory agencies in the name of competition has meant that the Medical Device Amendments of 1976 have not been implemented as the Congress intended.

THIS IS TRUE NO MATTER WHAT STAGE OF THE PROCESS OF MEDICAL DEVICE REGULATION WE EXAMINE -- PREMARKET APPROVAL, REPORTING ON UNSAFE DEVICES, OR RECALL OF DANGEROUS DEVICES.

Unlike drugs, not all devices are approved for safety and effectiveness. In fact quite the opposite -- 98% of devices now reach the market through loopholes in the law. Even among the potentially most dangerous devices, some 80% are not approved for safety and effectiveness prior to marketing.

FURTHER, WHEN DEVICES MALFUNCTION AND CAUSE INJURY OR EVEN DEATH, THE INFORMATION DOES NOT ALWAYS REACH THE FDA. THE GOVERNMENT ACCOUNTING OFFICE TELLS US THAT INFORMATION ON SERIOUS DEVICE FAILURES IN HOSPITALS REACHES THE FDA LESS THAN 1% OF THE TIME.

FINALLY, WHEN A DEVICE THAT IS ON THE MARKET IS ACTUALLY IDENTIFIED AS ONE THAT PRESENTS AN UNREASONABLE RISK OF HARM TO THE PUBLIC HEALTH, THE FDA'S POWER TO TAKE EFFECTIVE ACTION IS SEVERELY LIMITED. BEFORE THE FDA CAN SEEK REMEDIES SUCH AS REPLACEMENTS OF DEFECTIVE DEVICES, IT MUST PROVE NOT ONLY THAT THE PRODUCT IS UNREASONABLY DANGEROUS, BUT ALSO THAT IT DID NOT MEET THE STATE OF THE ART WHEN IT WAS DESIGNED AND MANUFACTURED.

WE HAVE SPENT THE LAST TWO YEARS DEVELOPING LEGISLATION TO ADDRESS THESE SHORTCOMINGS AND ASSIST THE FDA IN IMPLEMENTING THE MEDICAL DEVICE AMENDMENTS AS THE CONGRESS ORIGINALLY INTENDED. OUR BILL WOULD GREATLY IMPROVE FDA SCRUTINY OF DEVICES FOR SAFETY AND EFFECTIVENESS, PUT INTO PLACE A SYSTEM OF REPORTING BY HOSPITALS OF DEVICE FAILURES, AND STRENGTHEN THE FDA'S AUTHORITY TO ACT WHEN DANGEROUS DEVICES ARE IDENTIFIED.

Thus far, one of the consumer groups has been quite Helpful with technical suggestions for the legislation, as well as representing the consumer interests. I hope that as we proceed to move this legislation in the next month or so that all of you will take an active role in pressing for this much-needed reform.

MINIMUM HEALTH BENEFITS

I KNOW THAT YOU SHARE MY STRONG SENSE OF THE NEED TO IMPROVE ACCESS TO HEALTH CARE FOR SO MANY OF OUR CITIZENS.

I HAVE JOINED WITH SENATOR KENNEDY IN INTRODUCING-LEGISLATION DESIGNED TO ASSURE THAT AT LONG LAST NEARLY EVERY AMERICAN WORKER AND THE FAMILY OF THAT WORKER WILL HAVE HEALTH INSURANCE.

DURING THE PAST FORTY-ODD YEARS THERE HAVE BEEN GREAT IMPROVEMENTS IN HEALTH CARE COVERAGE. THE CORNERSTONE OF THAT EXPANSION HAS BEEN THE PRIVATE SECTOR PROVIDING HEALTH INSURANCE RELATED TO EMPLOYMENT. MANY OF YOU IN THIS ROOM HAVE UNDOUBTEDLY PLAYED A SIGNIFICANT ROLE IN THIS EXPANSION.

Unfortunately, Many People have Been Left uncovered even as Benefits for most workers have expanded.

BY LINKING HEALTH INSURANCE TO EMPLOYMENT, TWO LARGE GROUPS WERE LEFT OUT -- RETIRED PERSONS 65 AND OVER, AND PEOPLE UNABLE

TO WORK BECAUSE THEY HAD DISABILITIES OR WERE SINGLE PARENTS WITH SMALL CHILDREN. THE FEDERAL GOVERNMENT RECOGNIZED THIS PROBLEM OVER TWENTY YEARS AGO, AND ENACTED MEDICARE AND MEDICAID.

NEITHER PROGRAM HAS BEEN PERFECT, BUT BOTH HAVE PROVIDED MILLIONS OF PEOPLE WITH NEEDED HEALTH CARE.

OUR LEGISLATION DEALS WITH THE RAPIDLY GROWING NUMBER OF PEOPLE WHO ARE NOT COVERED UNDER EITHER MEDICAID OR MEDICARE OR UNDER INSURANCE PROVIDED IN THE WORKPLACE.

ESTIMATES OF THE SIZE OF THE POPULATION WITH NO HEALTH INSURANCE ARE DISCOURAGINGLY LARGE -- THIRTY-SEVEN MILLION BY MOST RECENT ESTIMATES. WHAT HAS COME AS AN UNHAPPY SURPRISE IS HOW MANY OF THE UNINSURED ARE PEOPLE WITH JOBS, AND THEIR FAMILIES.

NEARLY TWO OUT EVERY THREE PEOPLE WITHOUT HEALTH INSURANCE ARE FROM FAMILIES WHERE THE HEAD OF THE HOUSEHOLD IS EMPLOYED.

In some ways, what this means is that having health insurance coverage now is to some extent a matter of Luck. If you're fortunate enough to work for a large manufacturing firm or retailer, you're also likely to have good health insurance coverage. But if you work just as hard and have just as many responsibilities, but happen to work for a smaller company you are more likely to have no insurance.

WE ALL KNOW THE SERIOUS HUMAN CONSEQUENCES OF BEING WITHOUT HEALTH INSURANCE -- PEOPLE WITHOUT INSURANCE GET TO A DOCTOR AND GET INTO A HOSPITAL BARELY HALF AS OFTEN AS PEOPLE WITH INSURANCE. WORST OF ALL, THEY ARE MORE LIKELY TO GET SICK IN THE FIRST PLACE AND THEN PUT OFF SEEKING CARE UNTIL THEIR ILLNESS GETS SERIOUS.

THERE ARE ALSO SERIOUS ECONOMIC CONSEQUENCES OF HAVING SUCH A LARGE POPULATION OF UNINSURED PEOPLE. THESE CONSEQUENCES AFFECT HOSPITALS AND DOCTORS, BUT THEY ALSO AFFECT EMPLOYERS WHO DO PROVIDE HEALTH BENEFITS AND INSURERS WHO PAY HEALTH CARE BILLS.

HOSPITALS FACE A GROWING PROBLEM OF UNCOMPENSATED-CARE, WHEN PEOPLE WITHOUT INSURANCE ACTUALLY GET TO THE HOSPITAL FOR TREATMENT. EMPLOYERS WHO PAY FOR HEALTH CARE FOR THEIR WORKERS NOW REALIZE THAT PART OF THEIR HEALTH BILLS GOES TOWARD CROSS-SUBSIDIZING HEALTH CARE FOR THE UNINSURED.

EMPLOYERS WHO PROVIDE HEALTH BENEFITS ALSO PAY FOR COVERAGE FOR MANY WORKING SPOUSES OF THEIR EMPLOYEES -- AGAIN PICKING UP THE TAB FOR EMPLOYERS WHO DON'T PROVIDE HEALTH BENEFITS.

THIS SITUATION IS INTOLERABLE. IT IS BAD HEALTH POLICY AND EQUALLY BAD ECONOMIC POLICY. UNLESS THE CONGRESS ACTS, MORE AND MORE PEOPLE WILL FIND THEMSELVES WITHOUT ADEQUATE HEALTH INSURANCE. AND MORE AND MORE BUSINESSES WILL FIND THEIR HEALTH CARE COSTS GROWING FOR REASONS THAT ARE BEYOND THEIR CONTROL.

THE LEGISLATION THAT WE HAVE INTRODUCED, THE "MINIMUM HEALTH BENEFITS FOR ALL WORKERS ACT," H.R. 2508, WILL GO A LONG WAY TOWARD CORRECTING THESE INEQUITIES. THIS LEGISLATION BUILDS UPON OUR STRONG PRIVATE SECTOR TRADITION OF EMPLOYMENT-RELATED INSURANCE.

NEARLY ALL WORKERS WILL BE GUARANTEED BASIC HEALTH INSURANCE COVERAGE FOR THEMSELVES AND THEIR FAMILIES. EMPLOYERS AND EMPLOYEES WILL SHARE THE COSTS. THE MOST IMPORTANT PREVENTIVE SERVICES -- PRENATAL AND WELL-BABY CARE -- WILL BE FULLY COVERED. AND EVERY WORKER AND FAMILY MEMBER WILL BE PROTECTED AGAINST THE COSTS OF CATASTROPHIC ILLNESS.

EVEN UNDER THIS PROPOSAL, NOT EVERY AMERICAN WILL YET HAVE ADEQUATE HEALTH INSURANCE. SOME PEOPLE WILL STILL HAVE TO BE INCORPORATED INTO FEDERALLY FUNDED PROGRAMS. NOT EVERY NEEDED HEALTH SERVICE WILL BE PROVIDED. BUT IN VIEW OF THE BUDGET LIMITATIONS WE FACE NOW AND INTO THE FORESEEABLE FUTURE, WE WILL NEED TO BUILD ON PRIVATE SECTOR COVERAGE WHEREEVER WE CAN, AND DIRECT PUBLIC EXPENDITURES TO TARGETED PROBLEMS.

PROGRESS IN FEDERAL PROGRAMS

WITH REGARD TO FEDERALLY FUNDED PROGRAMS, THERE HAS BEEN A BIT OF PROGRESS WITH LEGISLATION ON SEVERAL FRONTS, THOUGH NOT LL THAT WE HAD HOPED FOR. IN MEDICAID, WE ARE CONTINUING TO EXPAND THE PROGRAM TO INCLUDE MORE LOW-INCOME WOMEN AND CHILDREN.

STATES WILL HAVE THE OPTION TO PROVIDE COVERAGE FOR PEOPLE IN THOSE CATEGORIES UP TO 185% OF THE FEDERAL POVERTY LEVEL. STATES MUST COVER CHILDREN UP TO AGE 6 WHO MEET STATE AFDC STANDARDS, WHICH ARE GENERALLY WELL BELOW THE POVERTY LEVEL.

WE ALSO TRIED TO PROVIDE FOR EXTENDED MEDICAID COVERAGE FOR PEOPLE WHO GET JOBS AND GO OFF OF WELFARE, BUT THAT WAS NOT ADOPTED. IT REMAINS A GOOD IDEA, THOUGH, AND AN ESSENTIAL PART OF ANY MEANINGFUL WELFARE REFORM PACKAGE. IT IS A PROGRAM I INTEND TO CONTINUE TO FIGHT FOR. I HOPE I'LL HAVE YOUR HELP.

Finally, I should note we are about to begin the House-Senate conference on legislation providing protection against catastrophic health care expenses, for Medicare beneficiaries. One of the most significant parts of this legislation is the coverage provided for prescription drugs after a \$500 deductible. It expands Medicare into one of the last major uncovered benefit areas that our Medicare population needs.

WHILE BOTH THE HOUSE AND SENATE BILL CONTAIN A DRUG BENEFIT, THE SENATE'S DOES NOT PROVIDE FULL COVERAGE UNTIL 1993. THAT'S

TOO LITTLE, TOO LATE. SIX MILLION MEDICARE BENEFICIARIES ARE SPENDING OVER \$1,000 A YEAR ON PRESCRIPTION DRUGS. THEY NEED HELP NOW.

WE LOOK FORWARD TO YOUR INVOLVEMENT AS WE ADDRESS THESE
IMPORTANT QUESTIONS, AND I APPRECIATE KNOWING THE PERSPECTIVE OF
THE CONSUMER GROUPS:

CONSUMER PRODUCT SAFETY COMMISSION

There are many, many other issues of concern to this Congress where your involvement will be needed. First, I am hopeful that Congress will finally enact legislation to reauthorize the Consumer Product Safety Commission (CPSC). With your help, last year we saw a strong House bill (H.R. 3343) favorably reported from Subcommittee.

THE "CONSUMER PRODUCT SAFETY IMPROVEMENT ACT" PROMISES TO REJUVENATE AND RESTORE PUBLIC CONFIDENCE IN THIS STRUGGLING AND EMBATTLED REGULATORY AGENCY. IF ENACTED, THIS LEGISLATION WILL FINALLY END THE EROSION IN PERSONNEL AND FINANCES THAT HAVE SO CRIPPLED THE CPSC'S EFFECTIVENESS AND SHATTERED STAFF MORALE DURING THE REAGAN YEARS.

Preserving the rights of consumers to seek legal redress is critical to our constitutional system of due process. But

PRODUCT LIABILITY ACTIONS ARE NOT AN ALTERNATIVE TO A REGULATORY SYSTEM COMMITTED TO THE PREVENTION OF PRODUCT INJURIES BEFORE THEY OCCUR. IN 1988 LET US WORK TOGETHER TO SEE THAT THE ORIGINAL INTENT OF THE CONSUMER PRODUCT SAFETY ACT IS RESTORED. LET US LABOR TO ASSURE THAT PUBLIC EXPECTATIONS ARE FULFILLED AND THAT PUBLIC CONFIDENCE IN THIS VITAL INDEPENDENT REGULATORY COMMISSION IS JUSTIFIED.

FIRE-SAFE CIGARETTES

SECOND, WE NEED TO ENACT LEGISLATION TO ASSURE FIRE-SAFE CIGARETTES. IRONICALLY, THE MOST DANGEROUS CONSUMER PRODUCT SOLD IN THIS COUNTRY IS NOT REGULATED BY CPSC, FDA OR ANY HEALTH AND SAFETY AGENCY. IN FACT, THE PRODUCT IS VIRTUALLY UNREGULATED BY EITHER FEDERAL OR STATE LAW.

I KNOW YOU ARE ALL AWARE OF THE ADVERSE HEALTH EFFECTS OF TOBACCO IN GENERAL AND CIGARETTE SMOKING IN PARTICULAR.

CIGARETTES ARE THE LEADING CAUSE OF PREVENTABLE ILLNESS AND PREMATURE DEATH IN THE COUNTRY. THATS WHAT THE SURGEON GENERAL SAYS. CIGARETTES ARE ALSO THE LEADING CAUSE OF RESIDENTIAL HOME FIRE DEATH AND INJURY. THAT WHAT THE FIRE CONTROL EXPERTS SAY.

LEGISLATION ON THIS ISSUE, THE "FIRE SAFE CIGARETTE ACT", HAS BEEN INTRODUCED IN THE HOUSE BY JOE MOAKLEY AND MYSELF AND IN THE SENATE BY ALAN CRANSTON. THE BILLS REQUIRE THAT THE FEDERAL

GOVERNMENT DEVELOP AND ISSUE A MANDATORY FIRE SAFETY STANDARD FOR CIGARETTES. THEY SHOULD BE PASSED.

FINALLY, LET ME REMIND THIS GROUP OF ANOTHER PROBLEM CRITICAL TO CONSUMERS.

DRUG PRICES AND GENERIC DRUGS

Finally, Let me remind this group of another problem critical to consumers——the high price of prescription drugs. In 1981, our nation's pharmaceutical companies embarked on a new pricing strategy. It is called "whatever the market will bear."

Unfortunately, when it comes to essential prescription drugs, customers have no choice. They will bear whatever is charged.

And consumer costs have skyrocketed. From 1981 to 1986, the Consumer Price Index increased 28 percent, but drug manufacturer wholesale prices rose 79 percent. Many of the top-selling drugs rose even faster.

THE DRUG COMPANIES CLAIM THEIR PRICE INCREASES ARE JUSTIFIED BY EVER-INCREASING COSTS OF RESEARCH AND DEVELOPMENT, BUT AT A HEARING BEFORE MY SUBCOMMITTEE, IT BECAME OBVIOUS THEIR PRICES HAD RISEN 3 TIMES FASTER THAN NECESSARY TO FUND EVERY DOLLAR OF NEW RESEARCH AND DEVELOPMENT SPENDING.

AND PHARMACEUTICAL COMPANIES HAVE DONE MORE THAN JUST RAISE PRICES FOR OFF-PATENT DRUGS IN RESPONSE TO NEW MARKET PRESSURES.

MANY COMPANIES HAVE ALSO ENGAGED IN ANTI-GENERIC ACTIVITIES.

ON THE ONE HAND, MANY LARGE RESEARCH-ORIENTED COMPANIES ARE BUYING GENERIC FIRMS OR STARTING THEIR OWN GENERIC DIVISIONS. ON THE OTHER HAND, THEY ARE ENGAGING IN AN ANTI-GENERIC CAMPAIGN CALCULATED TO DISCOURAGE GENERIC USE AND TO BOOST CORPORATE REVENUES.

AN INDUSTRY THAT MAKES GENERICS IN PRIVATE WHILE LAMBASTING THEM IN PUBLIC WILL EVENTUALLY LOSE CREDIBILITY AND REPUTATION. TO THINK OTHERWISE IS CYNICAL, AND IT SHORTCHANGES THE AMERICAN PEOPLE.

CONCLUSION

FINALLY, I WANT TO EMPHASIZE HOW IMPORTANT YOUR ROLE IS TO OUR WORK. ALL THE SPECIAL INTERESTS ARE WELL REPRESENTED. VERY FEW PEOPLE ARE HERE IN WASHINGTON TO SPEAK OUT FOR THE INDIVIDUAL CITIZENS OF THIS COUNTRY. WE NEED AND WE APPRECIATE ALL THE HELP WE CAN GET FROM THE CONSUMER ORGANIZATIONS OF AMERICA.

. THANK YOU. I WILL BE DELIGHTED TO RESPOND TO ANY QUESTIONS.